



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Kathleen H. Selover
Director, Regulatory Affairs and Quality
The SmartPill Corporation
847 Main Street
Buffalo, New York 14203-1109

JAN 10 2017

Re: K092342

Trade/Device Name: SmartPill GI Monitoring System, Version 2.0
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: NYV
Dated: July 29, 2009
Received: August 4, 2009

Dear Ms. Selover:

This letter corrects our substantially equivalent letter of October 30, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SMARTPILL CORPORATION
510(k) SUBMISSION – SECTION 4
SMARTPILL GI MONITORING SYSTEM, VERSION 2.0

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number: not assigned

Device Name: SmartPill GI Monitoring System, version 2.0

Indications for Use:

The SmartPill GI Monitoring System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.

Gastric transit time (gastric emptying time, GET) is indicated for the evaluation of patients with suspected gastroparesis. Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia

Colonic transit time (CTT) is indicated for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Combined small and large bowel transit time (SLBTT) is used as a surrogate measure of colonic transit in patients with chronic constipation when colonic transit time alone cannot be determined.

The System measures pH, pressure, and temperature throughout the GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.

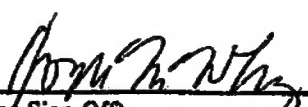
Not for use in pediatric patients.

☒ Prescription Use

OR

☐ Over-the-Counter Use _____ (Per 21CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K092342

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SMARTPILL CORPORATION
510(K) SUBMISSION – SECTION 5
SMARTPILL GI MONITORING SYSTEM, VERSION 2.0

SECTION 5: 510(K) SUMMARY

Date of Summary:

OCT 8 0 2008

Manufacturer:

The SmartPill Corporation
847 Main Street
Buffalo, NY 14203

Contact Information:

Phone: 716.882.0701, ext. 106
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Contact Person:

Kathleen H. Selover
Vice President, Regulatory Affairs and Quality
Assurance

Device Trade Name:

SmartPill GI Monitoring System, version 2.0

Device Common Name:

Gastrointestinal Motility System, Capsule

Trade/Device Name

SmartPill GI Monitoring System, version 2.0

Regulatory Class Regulation
Number

Unclassified
None

Product code

NYV

Predicate Device(s)

SmartPill GI Monitoring System and pH.p Capsule,
version 1.2
Konsyl Sitzmarks

SmartPill GI Monitoring System and pH.p Capsule,
version 2.0 is substantially equivalent to SmartPill GI
Monitoring System, version 1.2 and Konsyl Sitzmarks.

SMARTPILL CORPORATION
510(K) SUBMISSION – SECTION 5
SMARTPILL GI MONITORING SYSTEM, VERSION 2.0

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**Product
Description**

The SmartPill GI Monitoring System senses and records pH and pressure measurements from the entire length of the gastrointestinal tract for use by physicians to aid in the evaluation of gastrointestinal motility diseases and conditions. Sensors on board an ingestible capsule measure pH and pressure as the capsule travels the length of the GI tract. Measurements are transmitted from the capsule within the GI tract via ASK modulated RF signal at 434 MHz to a patient-worn Data Receiver and subsequently downloaded to PC for analysis and review. MotilGI™ Software performs data analyses automatically and provides the physician with a printable report containing regional gut transit times:
GET – Gastric emptying (transit) time
SBTT – Small bowel transit time
SLBTT – Combined small and large bowel transit time
CTT – Colonic transit time
WGTT – whole gut transit time

**Intended Use
Indications for Use**

The SmartPill GI Monitoring System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.

Gastric transit time (gastric emptying time, GET) is indicated for the evaluation of patients with suspected gastroparesis. Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia

Colonic transit time (CTT) is indicated for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Combined small and large bowel transit time (SLBTT) is used as a surrogate measure of colonic transit in patients with chronic constipation when colonic transit time alone cannot be determined.

The System measures pH, pressure, and temperature throughout the GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.

Not for use in pediatric patients.

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SMARTPILL CORPORATION
510(k) SUBMISSION – SECTION 5
SMARTPILL GI MONITORING SYSTEM, VERSION 2.0

Physical and Technical Comparisons	<p><i>Comparison to SmartPill GI Monitoring System:</i> Version 2.0 of the system is similar to Version 1.1; differences include an enhanced user interface for reviewing and analyzing the test and an expanded indications for use. Technical features of the two devices are the same.</p> <p><i>Comparison to Sitzmarks:</i> Version 2.0 of the system is technically different from Sitzmarks, however, the two devices share the indication for use of measuring and using colonic transit time to evaluate patients with chronic (severe) constipation.</p>
Performance Summary	<p>The performance of the SmartPill GI Monitoring System was tested in multiple bench tests to verify the accuracy and precision of the device. In addition, clinical testing was conducted to validate the device's indications for use. Results of these tests support the product's intended use, indications for use, performance and clinical claims.</p>
Safety Testing	
Biocompatibility	<p>All patient contacting materials were tested for biocompatibility in accordance with ISO-10993, Part I for a surface device that contacts breached or compromised surfaces for prolonged contact and plastic materials in accordance with USP <661>. Results of biocompatibility testing indicate that patient contacting materials are non-sensitizing, non-toxic, and non-irritating when used as directed.</p>
Electrical Safety	<p>Electrical safety was conducted and the system found to meet the requirements of IEC 60601-1</p>
Electromagnetic Compatibility	<p>EMC testing was tested and the system found to meet the requirements of IEC 60601-1-2</p>
Clinical Performance Testing	<p>Two prospective clinical studies were performed with the device. The first study established cutoff values for colonic and combined small large bowel transit time and the second study validated the cutoff values in symptomatic constipated patients.</p>